510(k) SUMMARY

Flower Orthopedics Corporation's
Rearfoot Plating Set

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Flower Orthopedics Corporation
100 Witmer Road, Suite 280
Horsham PA 19044

Phone: (215) 394-8903
Facsimile: (215) 394-8904

Contact Person: Gary Barnett
Date Prepared: December 19, 2013

Name of Device

Flower Rearfoot Plating Set

Common or Usual Name/Classification Name

The Flower Rearfoot Plating Set consists of bone plates classified under product code HRS (21 C.F.R. 888.3030, Single/multiple component metallic bone fixation appliance and accessories; Class II) and bone fixation screws classified under product code HWC (21 C.F.R. 888.3040, Smooth or threaded metallic bone fixation fastener; Class II).

Predicate Devices

Synthes USA, Locking Calcaneal Plates (K991407)
Smith & Nephew, VLP Foot Plating System (K110670, K090675)
Smith & Nephew, Peri-Loc Ankle Fusion Plating System (K120667)
Flower Orthopedics, Small and Medium Implant Set (K123562, K131657)

Intended Use / Indications for Use

The Flower Rearfoot Plating Set is intended to be used for internal fixation of fractures and reconstructions of bones of the rearfoot, including the calcaneus. Examples of these internal fixations and reconstructions include, but are not limited to extra-articular fractures, intra-articular fractures, joint depression fractures, tongue type fractures, severely comminuted fractures and osteotomies.

Device Description

The Flower Rearfoot Plating Set consists of the following components and accessories: calcaneal plates, MIS calcaneal plates, and calcaneal step osteotomy plates, all made of pure titanium compliant with ASTM F67. The system accepts locking and non-locking screws cleared via K123562 and K131657. The device is provided with general purpose instruments.

Technological Characteristics

The Flower Rearfoot Plating Set consists of the following components/configurations:

- Calcaneal Plate, Small, with a width of 23.4 mm and a length of 51.9 mm;
- Calcaneal Plate, Medium, with a width of 26.7 mm and a length of 57.9 mm;
- Calcaneal Plate, Large, with a width of 30.0 mm and a length of 63.8 mm;
- MIS Calcaneal Plate, Small, with a width of 23.4 mm and a length of 51.9 mm;
- MIS Calcaneal Plate, Medium, with a width of 26.7 mm and a length of 57.9 mm;
- MIS Calcaneal Plate, Large, with a width of 30.0 mm and a length of 63.8 mm; and
- Osteotomy Step Plates with a width of 16 mm, lengths of 17, 19.5, and 21 mm, and offsets of 5.0, 7.5, and 10.0 mm, respectively

Substantial Equivalence

The Flower Rearfoot Plating Set is substantially equivalent to the identified predicate devices.

The subject devices have the same intended uses/indications, technological characteristics, and principles of operation as the predicate devices. An engineering analysis was performed to demonstrate that the components in the Flower Rearfoot Plating Set provide appropriate mechanical strength for the claimed intended use. Also, a Finite Element Analysis (FEA) was performed to compare physiological loading of the subject and predicate devices. The FEA results confirmed that the subject devices have, at minimum, equivalent strength. Thus, the subject rear foot plates are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 27, 2014

Flower Orthopedics Corporation
Mr. Gary Barnett
RA/QA Manager
100 Witmer Road, Suite 280
Horsham, Pennsylvania 19044

Re: K133930
Trade/Device Name: Flower Rearfoot Plating Set
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: December 31, 2013
Received: January 03, 2014

Dear Mr. Barnett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K133930

Device Name: Flower Rearfoot Plating Set

Indications for Use:

The **Flower Rearfoot Plating Set** is intended to be used for internal fixation of fractures and reconstruction of bones of the rearfoot, including the calcaneus. Examples of these internal fixations and reconstructions include, but are not limited to extra-articular fractures, intra-articular fractures, joint depression fractures, tongue type fractures, severely comminuted fractures and osteotomies.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth D. Frank -S

Division of Orthopedic Devices

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